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burdensome with respect to State compliance.

- (4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.
- (5) A process for the periodic evaluation by the Secretary of programs under waivers.
- (b) *Purpose*. This part sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§33.102 Coordinated waiver process.

- (a) Coordination with applications for waivers under other Federal laws. A State may submit a single application to the Secretary of Health and Human Services for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Social Security Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for demonstrations under section 1115 of the Social Security Act. if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.
- (b) Coordinated process for section 1332 waivers. A State seeking a section 1332 waiver must submit a waiver application to the Secretary of Health and Human Services. Any application submitted to the Secretary of Health and Human Services that requests to waive sections 36B, 4980H, or 5000A of the Internal Revenue Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary of Health and Human Services to the Secretary to be reviewed in accordance with this part.

§ 33.104 Definitions.

For the purposes of this part:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of Health and Human Services have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 33.108(f).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with §33.112.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 33.108 Application procedures.

- (a) Acceptable formats for applications. Applications for initial approval of a section 1332 waiver shall be submitted in electronic format to the Secretary of Health and Human Services.
- (b) Application timing. Applications for initial approval of a section 1332 waiver must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.
- (c) Preliminary review. Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of Health and Human Services, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of Health and Human Services have made the preliminary determination that the application is complete.
- (1) The Secretary and the Secretary of Health and Human Services will complete the preliminary review of the application within 45 days after it is submitted.
- (2) If the Secretary and the Secretary of Health and Human Services determine that the application is not complete, the Secretary of Health and Human Services will send the State a written notice of the elements missing from the application.
- (3) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.
- (d) Notification of preliminary determination. Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary of Health and Human Services will send the State a written notice informing the State that the Secretary and the Secretary of Health and